the sponsor, are submitted to the testing laboratory for analysis and where final results are graded, scores are recorded and provided to participants, and scores for participants are evaluated for acceptance.

*Responsible official.* The individual designated by an entity to act on its behalf. This individual must have the authority and control to ensure compliance with the regulations in this part.

*Specimen.* A sample of material collected for use in testing, such as tissues, gastrointestinal contents, feces, bodily fluids (blood, serum, etc.), soil, water, feed or feed ingredients, swabs, cultures, and suspensions.

*State.* Any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

*Toxin.* The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes:

(1) Any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or

(2) Any poisonous isomer or biological product, homolog, or derivative of such a substance.

*United States.* All of the States.

*USDA.* The United States Department of Agriculture.

### § 121.2 Purpose and scope.

(a) This part sets forth the requirements for possession, use, and transfer of biological agents or toxins that have been determined to have the potential to pose a severe threat to both human and animal health, to animal health, or to animal products. The purpose of this part is to ensure the safe handling of such agents or toxins, and to protect against the use of such agents or toxins in domestic or international terrorism or for any other criminal purpose.

(b) Accordingly, this part provides that any individual or entity that possesses, uses, or transfers any agent or toxin listed in § 121.3 must register in accordance with § 121.7. To register, each entity must designate an individual who has the authority and control to ensure compliance with the regulations to be the responsible official. The responsible official must complete and submit the registration application package to APHIS or, for overlap agents or toxins, to APHIS or CDC. As part of registration, the responsible official, the entity, and, where applicable, the individual who owns or controls such entity will be subject to a security risk assessment by the Attorney General.

(c) The responsible official is responsible for ensuring compliance with the safety procedures in this part, including implementing the Biosafety and Security Plan in accordance with § 121.12, providing the proper training to individuals who handle or use agents or toxins listed in § 121.3, and providing proper laboratory facilities to contain and dispose of such agents or toxins. In addition, the responsible official is responsible for ensuring compliance with the safeguard and security measures in this part, including restricting access to only those individuals who have a legitimate need to handle or use agents or toxins and who have been approved in accordance with § 121.11, and transferring such agents or toxins only to registered individuals or entities in accordance with § 121.13.

### § 121.3 List of biological agents and toxins.

(a) Except as provided in paragraphs (f) and (g) of this section, the Administrator has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to both human and animal health, to animal health, or to animal products.

(b) *Overlap agents and toxins.*

*Bacillus anthracis*
Botulinum neurotoxins
Botulinum neurotoxin producing species of *Clostridium*
*Brucella abortus*
*Brucella melitensis*
*Brucella suis*
*Burkholderia mallei*